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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,723

07/26/2005

Ilan Ben-Oren

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EXAMINER

BAXTER, ZOE E

ART UNIT

PAPER NUMBER

3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/519,723

Applicant(s)

BEN-OREN ET AL.

Examiner

Zoe E. Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 100-127 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 126 and 127 is/are allowed.
- 6) ☒ Claim(s) 100, 101, 103, 105-107, 113-121 and 125 is/are rejected.
- 7) ☒ Claim(s) 102, 104, 108-112 and 122-124 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Specification*

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Double Patenting*

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

4. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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5. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 100 and 101 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 100 and 101 of the instant application is claiming at least one meal wherein two measurements taken at different volumes of the meal can be considered the equivalent of giving one meal taking a measurement and giving a second meal and taking a measurement as recited in claim 16 of the copending application. One meal with a measurement at two volumes is essentially two meals.

7. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claim 103 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because 103 of the instant application is claiming a method for the evaluation of gastric accommodation in a subject comprising the steps of administering at least two meals performing at least two measurements of a gastric emptying parameter and evaluating the gastric accommodation. Although this is broader than claim 16 of the copending application, wherein the method administers two meals

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claim 103 of the instant application is an obvious variant of claim 16 of the copending application and is therefor not patentably distinct.

9. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 105 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 105 of the instant application is a method of evaluating gastric accommodation comprising the steps of administering at least two meals performing at least two measurements of a gastric emptying parameter and evaluating the gastric accommodation wherein the volume of the second meal is larger than the first. Although this is broader than claim 16 of the copending application, wherein the method administers two meals claim 105 of the instant application is an obvious variant of claim 16 of the copending application and is therefor not patentably distinct.

11. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 106 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 16 of the copending application claims the second meal is larger than the first but does not state the it is twice the volume of the

first it would be an obvious design choice since there is no stated advantage, is not used for a particular purpose and doesn't solve a stated problem, there for claim 106 of the instant application would be considered an obvious design choice over claim 16 of the copending application and would not be patentably distinct from claim 16 of the copending application.

13. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claim 107 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because in order for claim 26 of the copending application to be able to measure gastric emptying using a breath test it is obvious to one of ordinary skill in the art that a marker must be present in the meal.

15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claim 113 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 16 of the copending application determines at least one characteristic of gastric emptying prior to administering a second liquid meal the method of claim 113 of the pending application also measures at least one characteristic of gastric emptying but not necessarily prior to the administering of the

second meal making claim 113 of the instant application broader than claim 16 of the copending application, therefore it is an obvious variant of claim 16 of the copending application and not patentably distinct.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claim 114 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 114 of the pending application is an obvious variant of claim 17 of the copending application in that the method of claim 114 of the instant application does not specify the measurement of the gastric emptying of the first meal is not necessarily before the second meal is ingested.

19. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claim 115 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 115 of the instant application indicates that the meal is at least 500ml and claim 18 of the copending application indicates the second meal is at least 750ml therefore the range of claim 115 of the copending application is within the range of claim 18 of the instant application.

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21. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. Claim 116 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 19 of the copending application determines at least one characteristic of gastric emptying prior to administering a second liquid meal the method of claim 116 of the pending application also measures at least one characteristic of gastric emptying but not necessarily prior to the administering of the second meal making claim 116 of the instant application broader than claim 19 of the copending application, therefor it is an obvious variant of claim 19 of the copending application and not patentably distinct..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claim 117 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-22 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 20 of the copending application indicates a meal wherein the predetermines pH is less than 3.0 as claimed in claim 117 of the instant application, claim 21 of the copending application claims the caloric value is at least 200 kilocalories which is at least 150 kilocalories as claimed in claim 117 in



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the instant application and claim 22 copending application claims the composition is isotonic as claimed in 117 of the instant application.

24. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claim 118 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 23 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 23 of the copending application determines at least one characteristic of gastric emptying prior to administering a second liquid meal the method of claim 118 of the pending application also measures at least one characteristic of gastric emptying but not necessarily prior to the administering of the second meal making claim 118 of the instant application broader than claim 23 of the copending application, therefor it is an obvious variant of claim 23 of the copending application and not patentably distinct..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claim 119 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 24 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 24 of the copending application determines at least one characteristic of gastric emptying prior to administering a second liquid meal the method of claim 119 of the pending application also measures at least one

characteristic of gastric emptying but not necessarily prior to the administering of the second meal making claim 119 of the instant application broader than claim 24 of the copending application, therefor it is an obvious variant of claim 24 of the copending application and not patentably distinct..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. Claim 120 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 25 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 25 of the copending application determines at least one characteristic of gastric emptying prior to administering a second liquid meal the method of claim 120 of the pending application also measures at least one characteristic of gastric emptying but not necessarily prior to the administering of the second meal making claim 120 of the instant application broader than claim 25 of the copending application, therefor it is an obvious variant of claim 25 of the copending application and not patentably distinct..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claim 121 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 115 of the instant application indicates that the

meal is at least 500ml and claim 18 of the copending application indicates the second meal is at least 750ml therefore the range of claim 115 of the copending application is within the range of claim 18 of the instant application.

29. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

30. Claim 125 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/784117. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 26 of the copending application determines at least one characteristic of gastric emptying prior to administering a second liquid meal the method of claim 125 of the pending application also measures at least one characteristic of gastric emptying but not necessarily prior to the administering of the second meal making claim 125 of the instant application broader than claim 26 of the copending application, therefor it is an obvious variant of claim 26 of the copending application and not patentably distinct..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Allowable Subject Matter***

31. Claims 102, 104, 108-112 and 122-124 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

32. Referring to claim 102 prior art of record fail to teach or fairly suggest a method of measuring gastric accommodation comprising the steps of: administering at least one meal, performing at least two measurements of gastric emptying and evaluating the gastric accommodation from measurements of gastric emptying parameters as a function of the volume of said meal.

33. Referring to claim 104 prior art of record fail to teach or fairly suggest a method of measuring gastric accommodation comprising the steps of: administering at least one meal, performing at least two measurements of gastric emptying and evaluating the gastric accommodation from measurements of gastric emptying parameters as a function of the volume of said meal wherein the first meal is larger than the second.

34. Referring to claims 108 prior art of record fail to teach or fairly suggest a method of determining gastric accommodation of a subject comprising the steps of administering at least one meal, measuring at least one gastric emptying characteristic of each meal and evaluating the gastric accommodation according to the deviation between the gastric emptying characteristics wherein a marker is detected by its presence in the exhaled breath of a subject.

35. Referring to claim 109 prior art of record fail to teach or fairly suggest a method of determining gastric accommodation of a subject comprising the steps of administering at least one meal, measuring at least one gastric emptying characteristic of each meal and evaluating the gastric accommodation according to the deviation between the gastric emptying characteristics wherein a marker is detected by its presence in the body of a subject.

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36. Referring to claim 110 prior art of record fail to teach or fairly suggest a method of determining gastric accommodation of a subject comprising the steps of administering at least one meal, measuring at least one gastric emptying characteristic of each meal and evaluating the gastric accommodation according to the deviation between the gastric emptying characteristics wherein a marker is detected by its presence in the gastro-intestinal tract of a subject.

37. Referring to claims 111 and 112 prior art of record fail to teach or fairly suggest a method of determining gastric accommodation of a subject comprising the steps of administering at least one meal, measuring at least one gastric emptying characteristic of each meal and evaluating the gastric accommodation according to the deviation between the gastric emptying characteristics wherein the meal comprises at least one of at least 150 kcalories, at least 5% lipid content, at least 10% carbohydrate content, at least 5% protein content and a pH of at least 3.

38. Referring to claim 122 prior art of record fail to teach or fairly suggest a method of determining gastric accommodation of a subject comprising the steps of administering a first liquid meal, administering a second liquid meal after first meal has begun emptying, measuring at least one gastric emptying characteristic of each meal and evaluating the gastric accommodation according to the deviation between the gastric emptying characteristics, wherein the marker is detected by its presence in the exhaled breath of a subject.

39. Referring to claim 123 prior art of record fail to teach or fairly suggest a method of determining gastric accommodation comprising the steps of administering a first

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liquid meal, administering a second liquid meal after first meal has begun emptying, measuring at least one gastric emptying characteristic of each meal and evaluating the gastric accommodation according to the deviation between the gastric emptying characteristics, wherein a marker is detected by its presence in the body of a subject.

40. Referring to claim 124 prior art of record fail to teach or fairly suggest a method of determining gastric accommodation of a subject comprising the steps of administering a first liquid meal, administering a second liquid meal after first meal has begun emptying, measuring at least one gastric emptying characteristic of each meal and evaluating the gastric accommodation according to the deviation between the gastric emptying characteristics, wherein a marker is detected by its presence in the gastro-intestinal tract of a subject.

41. Claims 126 and 127 are allowed. The following is a statement of reasons for the indication of allowable subject matter: Prior art of record fail to teach or fairly suggest a method for the evaluation of at least two gastric accommodation, gastric emptying and visceral sensitivity comprising the steps of administering a first liquid meal, administering a second liquid meal after the first meal has begun emptying, determining the gastric emptying rates of the first and second meal, utilizing the rates to determine gastric accommodation.

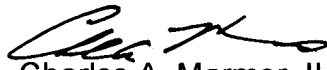
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**Conclusion**

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charles A. Marmor, II  
Supervisory Patent Examiner  
Art Unit 3735

ZEB